

**Notice of Allowability**

Application No.

10/826,466

Applicant(s)

ANDREWS ET AL.

Examiner

Marcia S. Noble

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Response to Non-Final, filed 3/1/2007.
2. ☒ The allowed claim(s) is/are 46, 49 and 53-61.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 46, 48, 49, and 53-61 are pending. Claims 46, 48, 55, 56, and 59 are amended by Applicant's response filed 3/1/2007. Claims 46, 48, 49, and 53-61 are under consideration.

### ***Preliminary Matters***

2. A proposed amendment to the claims set to reflect a claim set was drafted and Applicant's Representatives, David Scherer and Bret Field, were contacted by telephone on 5/8/2007, and the draft was sent for Applicant's consideration on the same day. Applicant accepted the proposed amendments which will follow in the Examiner's Amendment below.

3. The rejection of claims 46, 48, 49, and 50-61 under 35 U.S.C. 112, first paragraph for lack of enablement over the full scope is withdrawn.

The claims were deemed to not be enabled because the breadth of the claims encompassed improper controls for the method. The amendment to the claims as provide in the Examiner's Amendment now provide the proper comparative controls and therefore overcome the enablement rejection. Therefore, the rejection is withdrawn.

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4. The rejection of claims 46, 48, 49, and 53-61 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, is withdrawn.

The claims were rejected for omitting the essential steps to provide the proper comparative controls in the method. The amendment to the claims as provide in the Examiner's Amendment now provide the proper comparative controls and therefore overcome the rejection. Therefore, the rejection is withdrawn.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Authorization for this examiner's amendment was given in a telephone interview with David Scherer and Bret Field on 5/9/2007. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

46. (Currently Amended) A method of determining whether an agent inhibits GC-Box 5 repression of TERT activity in cultured cells, said method comprising:

(a) contacting said agent with a first expression system comprising a GC-Box 5 repressor binding site and a first coding sequence operably linked to a TERT promoter under conditions such that in the absence of said agent transcription of said coding sequence is repressed as compared to transcription in the presence of said agent;

(b) contacting said agent with a second expression system comprising a ~~second~~ said coding sequence operably linked to [[a]] said TERT promoter, wherein said second expression system ~~that does not comprise~~ [[a]] said GC-Box 5 repressor binding element-site;

wherein said first and second expression systems are cultured cells;

(c) determining whether transcription of said first-coding sequence in said first expression system is repressed in the presence of said agent as compared to transcription in the absence of said agent; and

(d) determining whether transcription of said coding sequence in said second expression system is altered in the presence of said agent as compared to transcription in the absence of said agent; and

(e) identifying said agent as an agent that inhibits GC-Box 5 repression of TERT transcription if transcription of said first-coding sequence in said first expression system is not repressed in the presence of said agent as compared to transcription in the absence of said agent and transcription of said second-coding sequence in said second expression system is not altered in the presence of said agent as compared to transcription in the absence of said agent.

47. (Canceled)

48. (Canceled)

49. (Original) The method according to Claim 46, wherein said agent is a small molecule.

50-52. (Canceled)

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53. (Previously Presented) The method according to Claim ~~48~~46, wherein said cultured cells does not express telomerase.

54. (Previously Presented) The method according to Claim 53, wherein said cultured cells ~~is~~are an MRC5 cells.

55. (Currently Amended) The method according to Claim 46, wherein said ~~first~~-coding sequence encodes a luciferase.

56. (Currently Amended) The method according to Claim 46, wherein said ~~first~~-coding sequence encodes a secreted alkaline phosphatase (SEAP).

57. (Previously Presented) The method according to Claim 46, wherein said agent is a biomolecule.

58. (Previously Presented) The method according to Claim 57; wherein said biomolecule is selected from the group consisting of peptides, proteins, nucleic acids, oligonucleotides, saccharides, fatty acids, steroids, purines, pyrimidines, and derivatives or structural analogs thereof.

59. (Currently Amended) The method according to Claim 46, wherein each of said ~~first~~ expression systems ~~is contained~~comprises in a vector.

60. (Previously Presented) The method according to Claim 59, wherein said vector is a plasmid.

61. (Previously Presented) The method according to Claim 59, wherein the vector is a viral vector.

*Conclusions*

5. No rejections of record remain and the amended claims as presented in the Examiners Amendment are deemed allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER